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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/866,033      | 05/25/2001  | Ellen R. Bolte       | 6917 P 002          | 4271             |

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/31/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/866,033

Applicant(s)

BOLTE, ELLEN R.

Examin r

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this c mmunication appears on the cover sheet with the c rrespondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_ .
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-14, drawn to a method of treating an individual exhibiting at least one symptom of a mental disorder, comprising administering an antimicrobial composition to inhibit the symptom of the disorder, and to a kit for treating an individual exhibiting at least one symptom of a mental disorder, the kit comprising an antimicrobial composition, classified in class 514, subclass 202, class 530, subclass 324, and class 536, subclass 7.2.

Should Group I be elected, applicant is required to select one mental disorder from claim 2 or 9. Each mental disorder is considered patentably distinct because the diagnosis of each disorder is different, each disorder can be treated with a different drug and has different outcome for the treatment. Applicant is also required to select one type of antimicrobial composition from claim 3 or 4, or, from claim 10 or 11. Each type of antimicrobial composition is considered patentably distinct because each type of compound has different chemical property and produces different effect in the method of treatment. This is not species election.

II. Claims 15-36, drawn to a method of treating an individual exhibiting at least one symptom of a mental disorder, comprising administering an antimicrobial composition to inhibit the symptom of the disorder and administering a probiotic mixture to replenish gastrointestinal microbes, and to a kit for treating an individual exhibiting at least one symptom of a mental disorder, the method comprising administering an antimicrobial composition to inhibit the

Art Unit: 1653

symptom of the disorder and administering a probiotic mixture to replenish gastrointestinal microbes, classified in class 514, subclass 202, and class 530, subclass 324, and class 424, subclass 93.3.

Should Group II be elected, applicant is required to select one mental disorder from claim 16 or 27. Each mental disorder is considered patentably distinct because the diagnosis of each disorder is different, each disorder can be treated with a different drug and has different outcome for the treatment. Applicant is also required to select one type of antimicrobial composition from claim 17 or 18, or, from claim 28 or 29. Each type of antimicrobial composition is considered patentably distinct because each type of compound has different chemical property and produces different effect in the method of treatment. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Inventions I and II are distinct from each other because each group contains different materials and have different effects. For example, Invention I contains an antimicrobial composition, while Invention II contains an antimicrobial composition and a probiotic mixture.

The method of Invention I is distinct from the method of Invention II because the method steps and outcomes are wholly different between Inventions I and II. For example, Invention I is a method to inhibit the at least one symptom of the disorder, while Invention II is a method to inhibit the at least one symptom of the disorder and to replenish gastrointestinal microbes.

The product of Invention I is distinct from the method of Invention II because the product of Invention I can be neither made by nor used in the method of Invention II.

Art Unit: 1653

The product of Invention II is distinct from the method of Invention I because the product of Invention II can be neither made by nor used in the method of Invention I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the recognized divergent subject matter, and because Inventions I and II require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

May 29, 2002